510(k) Summary

NOV 1 5 2001

K013608

Date: September 20, 2001

Submitter's Name: Toshiba America Medical Systems, Inc.
Submitter's Address: P.O. Box 2068, 2441 Michelle Drive,
Tustin, CA 92781-2068

Submitter's Contact: Diana Thorson, Senior Regulatory Affairs Specialist,
(714) 730-5000, Extension 4121

Device Proprietary Name: Digital Radiography System, Model DFP-8000D
Classification Name: Image Intensified Fluoroscopic X-Ray System (Accessory)
Common Name: Image Processor
[Fed. Reg. No. 892.1650, Product Code: JAA]

Predicate Device: Toshiba DFP-2000A/A4 (K941611)

Description of this Device:

The Digital Radiography System, Model DFP-8000D is a Digital Radiography Processor used in diagnostic X-ray angiography systems. This system processes, displays, and records digital images obtained from the detectors of X-ray TV systems (such as CCD cameras), and replays the recorded images.

Summary of Intended Uses:

The Digital Radiography System, Model DFP-8000D is a Digital Radiography Processor used in diagnostic X-ray angiography systems. This system processes, displays, and records digital images obtained from the detectors of X-ray TV systems (such as CCD cameras), and replays the recorded images for image diagnosis. This system is intended for use in diagnostic and interventional procedures for cardiac blood vessels, cerebral blood vessels, abdominal blood vessels, and lower limb blood vessels. This device employs no intended uses that are not in cleared devices already found in the marketplace.

Technological Characteristics:

The technological characteristics of this device are the similar to that of the predicate device. The differences in technological characteristics are due to the employment of updated technologies such as updated image processing, image memory, operating system, and CPU.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 15 2001

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K013608
Trade/Device Name: Digital Radiography System
Model DFP-8000D
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified
Fluoroscopic x-ray system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving
And communications system
Regulatory Class: II
Product Code: 90 JAA
Product Code: 90 LLZ
Dated: October 30, 2001
Received: October 31, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 1 5 2001

510 (k) Number (If Known): K013608

Device Name: Toshiba Digital Radiography System, Model DFP-8000D

Indications For Use:

The Digital Radiography System, Model DFP-8000D is a Digital Radiography Processor used in diagnostic X-ray angiography systems. This system processes, displays, and records digital images obtained from the detectors of X-ray TV systems (such as CCD cameras), and replays the recorded images for image diagnosis. This system is intended for use in diagnostic and interventional procedures for cardiac blood vessels, cerebral blood vessels, abdominal blood vessels, and lower limb blood vessels.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-the-Counter Use _____

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510 (k) Number: K013608